04-14-03 60462100 . 041103

Docket No. 3564-4028
Express Mail No. EV 170 404 835 US

04/11/03 jc961 U.S. PTO

J1131 U.S. PTO 60/462100 04/11/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR §1.53(c)(1).

INVENTOR(s)/APPLICANT(s)

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TITLE

Dietary Supplements Containing Extracts of Cinnamon and Methods of Using Same to Enhance Nutrient Transport and Promote Weight Loss

CORRESPONDENCE ADDRESS

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27123
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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification Number of Pages [11]
☐ Drawings(s) Number of Sheets [_____]
☐ [_____]Claims(s) Number of Sheets [_____] *(not required)*
☐ Small Entity Status is/has been claimed.
☐ Assignment
☐ Other:

METHOD OF PAYMENT *(check one)*

☒ A check or money order is enclosed to cover the Provisional filing fees.

☐ The Commissioner is hereby authorized to charge the filing fees and credit Deposit Account No. 13-4500, Order No. _____.

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PROVISIONAL FILING FEE AMOUNT ($)

☐ $80.00 (small entity)
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No ☐ Yes, the name of the U.S. Government agency and the Government contract number are:

☒ Additional inventors are being named on separately numbered sheets attached hereto

Respectfully submitted,

Signature Kimber L. Blackburn Date April 11, 2003

Type or Print Name Kimber L. Blackburn Registration No. 41,380

PROVISIONAL APPLICATION FILING ONLY

766604 v1

[redacted]

Docket No. 3564-4028

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Peter Miller and Timothy Romero

Group Art Unit: To Be Assigned

Serial No.: To Be Assigned

Examiner: To Be Assigned

Filed: Herewith (April 11, 2003)

For: DIETARY SUPPLEMENTS CONTAINING EXTRACTS OF CINNAMON AND METHODS OF USING SAME TO ENHANCE NUTRIENT TRANSMPORT AND PROMOTE WEIGHT LOSS

EXPRESS MAIL CERTIFICATE

Express Mail Label No.: **EV 170 404 835 US**

Date of Deposit: **April 11, 2003**

I hereby certify that the following attached paper(s) and/or fee

1. Provisional Application Cover Sheet (1 page);
2. Provisional Application (12 pages);
3. Provisional Application Filing Fee (check for $160.00)
4. Return Postcard

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to: **BOX: PROVISIONAL PATENT APPLICATION**, Commissioner for Patents, Washington, DC 20231.

Albert Isles

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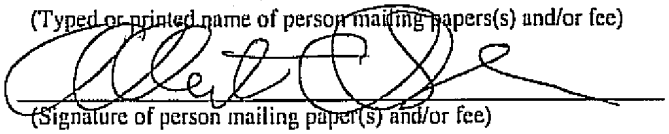

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Peter J. Miller		
Serial No.:	To Be Assigned		
Filed:	Herewith		
For:	FOOD SUPPLEMENTS CONTAINING 4-HYDROXYISOLEUCINE AND CREATINE	**Docket No.**	54259-246941

Box Provisional Patent Application
Commissioner for Patents
Washington, D.C. 20231

Via Express Mail Label No. EV102572848US

TRANSMITTAL LETTER

Enclosed for filing are the following papers in connection with the above-identified provisional patent application:

- **New Provisional Patent Application consisting of: a Provisional Application Cover Sheet and 6 page(s) of Specification;**
- **Postcard.**
  A self-addressed return postcard in accordance with M.P.E.P. Section 503 itemizing all of the above-referenced documents filed with the United States Patent and Trademark Office.

Respectfully Submitted,

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Dated: April 22, 2002
M2:20457913.01

M2:20457913 01

FOOD SUPPLEMENTS
CONTAINING 4-HYDROXYISOLEUCINE AND CREATINE

The present invention is directed to a dietary or food supplement that is a combination of 4-hydroxyisoleucine and creatine or derivatives of these two compounds. This invention also includes methods for altering or modifying the body's utilization of nutrients using 4-hydroxyisoleucine or its derivatives, and methods for altering or modifying the body's utilization of nutrients using the combination of 4-hydroxyisoleucine and creatine, or derivatives thereof.

4-hydroxyisoleucine is an amino acid that is naturally found in very low levels in Fenugreek seeds. It is possible to obtain purified amounts of this compound or material using common extraction processes. This material is presently commercially available from companies such as TSI and Pure World Botanicals.

Creatine (also known as N-methyl-N-guanyl glycine or (alpha methyl guanido) acetic acid) is a compound derived from amino acids, and is produced naturally in the body. Creatine can also be obtained from food such as meat and fish. Commercially available creatine derivatives include creatine phosphate, creatine citrate, magnesium creatine, alkaline creatine, creatine pyruvate, glycocyamine, creatine pyruvates, and creatine hydrates such as creatine monohydrate. Supplements containing creatine are commonly recommended in order to enhance muscle size, strength and even cell volume.

The dietary or food supplements of the present invention comprise a combination or a mixture of 4-hydroxysoleucine or a derivative thereof and creatine or a derivative thereof. A number of particular embodiments are within the scope of this invention. In one embodiment, the dietary or food supplement includes 4-hydroxyisoleucine or a derivative thereof and creatine or a salt, hydrate, ester or metabolite thereof. In another embodiment, the dietary or food supplement includes 4-hydroxyisoleucine or a derivative thereof and creatine monohydrate, citrate, phosphate or a derivative thereof. In still another embodiment, the dietary or food supplement comprises from about 0.5 mg to about 100 mg 4-hydroxyisoleucine or a derivative thereof per gram of supplement and from about 0.02 grams to about 0.80 grams of creatine or a derivative thereof per gram of supplement. Supplements that include these listed amounts of 4-hydroxyisoleucine

generally provide an augmented amount of this compound that is not provided by typical sources of 4-hydroxyisoleucine, such as Fenugreek seeds.

In still another embodiment, the dietary or food supplement includes a simple sugar such as, for example, maltose or dextrose. In still further embodiments of this invention, the dietary or food supplement also includes additional additives such as glutamine, glutamine peptides, taurine, phosphate, glycocyamine, chromium, D-pinitol, arginine, leucine, myo-inositol, citrulline, alanine, carnitine, or mixtures thereof.

The present invention also includes methods for using a dietary or food supplement that includes a combination or a mixture of 4-hydroxyisoleucine or its derivatives and creatine or its derivatives. One embodiment of this method includes administering to an athlete a dietary or food supplement comprising 4-hydroxyisoleucine or a derivative thereof, and creatine or a derivative thereof. Another embodiment of a method is administering a supplement in an amount that provides from about 20 mg to 2 grams of 4-hydroxyisoleucine or a derivative thereof and from about 2 grams to 30 grams of creatine or a derivative thereof to an athlete on a daily basis. In yet another embodiment, a supplement containing from about 0.5 mg to about 100 mg 4-hydroxyisoleucine or a derivative thereof per gram of supplement and from about 0.02 grams to about 0.80 grams of creatine per gram of supplement is administered to an athlete. In still another embodiment, the supplement is administered in an amount of about 15 grams to 400 grams per day. In still another embodiment, the supplement includes simple sugars such as maltose or glucose or a combination thereof. In yet another embodiment, the dietary or food supplement is mixed with water to provide a liquid beverage or is otherwise delivered in an aqueous form. In yet another embodiment, the dietary or food supplement is delivered in a gel or other non-aqueous format.

Still another method of this invention includes enhancing an athlete's muscle size and strength by administration to the diet of an athlete a supplement comprising 4-hydroxyisoleucine or a derivative thereof, and creatine or a derivative thereof. Another embodiment of this method is administering to the athlete a supplement containing from about 0.5 mg to about 100 mg 4-hydroxyisoleucine or a derivative thereof per gram of supplement and from about 0.02 grams to about 0.80 grams of creatine per gram of supplement is administered to an athlete.

Another method of this invention includes using a combination of creatine and 4-hydroxyisoleucine to increase serum insulin levels and to potentiate greater creatine transport. One embodiment of this method includes administering to a human subject a dietary or food supplement comprising 4-hydroxyisoleucine or a derivative thereof, and creatine or a derivative thereof. Another embodiment of a method is administering a supplement in an amount that provides from about 20 mg to 2 grams of 4-hydroxyisoleucine or a derivative thereof and from about 2 grams to 30 grams of creatine or a derivative thereof to a human subject on a daily basis. In yet another embodiment, a supplement containing from about 0.5 mg to about 100 mg 4-hydroxyisoleucine or a derivative thereof per gram of supplement and from about 0.02 grams to about 0.80 grams of creatine per gram of supplement is administered to increase serum insulin and potentiate greater creatine transport. In still another embodiment, the supplement is administered in an amount of about 15 grams to 400 grams per day. In still another embodiment, the administered supplement includes carbohydrates, which can be complex carbohydrates or simple carbohydrates such as maltose or glucose or a combination thereof.

Those skilled in the art understand that glycogen and amino acid storage are key regulators of protein synthesis in the cell. Also, greater glycogen storage capacity typically leads to greater muscle endurance, thus allowing extended work-out periods and enhanced physical performance. In addition, delivering additional amino acids potentially enhances protein synthesis within the cell thereby increasing muscle mass and performance/strength.

Yet another method of this invention includes using supplementary 4-hydroxyisoleucine to facilitate greater overall nutrient transport. The nutrients for which this method is particularly applicable include carbohydrates, proteins, amino acids, creatine, or other nutrients which may be provided by known dietary supplements. One embodiment of this method includes administering to a human subject a dietary or food supplement comprising 4-hydroxyisoleucine or a derivative thereof. Another embodiment of a method is administering a supplement in an amount that provides from about 20 mg to 2 grams of 4-hydroxyisoleucine or a derivative thereof to a human subject on a daily basis. In yet another embodiment, a supplement containing from about 0.5 mg to about

100 mg 4-hydroxyisoleucine or a derivative thereof per gram of supplement is administered to facilitate greater overall nutrient transport. In still another embodiment, the supplement is administered in an amount of about 15 grams to 400 grams per day.

Research studies on animals have shown that 4-hydroxyisoleucine causes a dose-dependent response with glucose administration, resulting in increases in serum insulin levels and a subsequent drop in glucose levels. In one study, the administration of 4-hydroxyisoleucine at a level of 18mg/kg elicited a two- to three-fold greater insulin response over a typical glucose load. Additionally, the response was shown to be effective not only through intravenous administration but through oral administration of this compound. This finding indicates that 4-hydroxyleucine is suitable for supplemental oral delivery.

The research data shows that 4-hydroxyisoleucine can significantly alter and improve the body's utilization of nutrients that are insulin-dependent or insulin-mediated. 4-hydroxyisoleucine could also be used in the treatment of diabetes, specifically Type II, due to its glucose clearance effects. The disclosure of the following articles is hereby incorporated by reference in their entirety:

> Broca C, Gross R, Petit P, Sauvaire Y, Manteghetti M, Tournier M, Masiello P, Gomis R, Ribes G. 4-Hydroxyisoleucin: experimental evidence of its insulinotropic and antidiabetic properties. American Journal of Physiology 1999, 277:E617-E623;
>
> Sauvaire Y, Petit P, Broca C. 4-Hydroxyisoleucine: A Novel Amino Acid Potentiator of Insulin Secretion. Diabetes 1998, 47:206-210.

It is believed that creatine transport is mediated through the insulin pathways due to the responses seen after the ingestion of carbohydrates, specifically glucose. Since 4-hydroxyisoleucine has a direct effect on potentiating the release of insulin through the beta cells of the pancreas, this in combination with another insulin potentiating sugar or other compound could reduce the glucose level and impact creatine transport into the muscle cell. In addition, 4-hydroxyisoleucine may deliver nutrients (such as carbohydrates, proteins or other non-macro nutrients) to human cells faster and in greater quantities than naturally occurring physiologically following a period of exercise (when

glucose distribution is shifted preferentially to deliver to muscle tissue rather than adipose tissue).

Accordingly, the dietary or food supplements of the present invention comprise a mixture of 4-hydroxyisoleucine or a derivative thereof with creatine or a derivative thereof, for example a salt, ester, hydrate, or metabolite thereof. Commercially available creatine derivatives include creatine phosphate, creatine citrate, magnesium creatine, alkaline creatine, creatine pyruvate, glycocyamine, creatine pyruvates, and creatine hydrates such as creatine monohydrate.

In one embodiment, between 1 mg/ kg bodyweight to 30 mg/kg bodyweight of 4-hydroxyisoleucine is taken daily. In another embodiment, up to about 50 mg/kg is taken daily. The amount of 4-hydroxyisoleucine that would be used by a typical person is between 20 mg to 2 grams of 4-hydroxyisoleucine per day. Using levels lower than this would probably not yield an efficacious result, while using higher levels could cause negative hypoglycemic effects, or extremely low blood sugar levels.

In another embodiment of this invention, the amount of creatine that would be used by a typical person would be a typical recommended amount that ranges between 2 grams to 30 grams per day. Thus, in a particular embodiment, the present dietary or food supplement comprises from about 0.5 mg to about 100 mg 4-hydroxyisoleucine (or derivative thereof) per gram of supplement and from about 0.02 grams to about 0.80 grams of creatine (or derivative thereof) per gram of supplement.

Also, several compounds are known to have similar ergogenic properties relating to glucose disposal, or insulin sensitivity. For example, arginine and leucine are known stimulators of insulin release whereas D-pinitol works at the cell site to increase glucose transporters to promote a more rapid uptake of glucose into the cell. These compounds used in connection with 4-hydroxyisoleucine or a derivative thereof promote greater nutrient/creatine uptake into the cells.

What is claimed is:

A dietary or food supplement comprising about 0.5 mg to about 100 mg 4-hydroxyisoleucine or derivatives thereof per gram of supplement and about 0.02 grams to about 0.80 grams of creatine or derivatives thereof per gram of supplement.

PATENT

Docket No. 3564-4028

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PROVISIONAL PATENT APPLICATION

For

DIETARY SUPPLEMENTS CONTAINING EXTRACTS OF CINNAMON AND METHODS OF USING SAME TO ENHANCE NUTRIENT TRANSPORT AND PROMOTE WEIGHT LOSS

BY

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EV 170 404 835 US

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DIETARY SUPPLEMENTS CONTAINING EXTRACTS OF CINNAMON AND METHODS OF USING SAME TO ENHANCE NUTRIENT TRANSPORT AND PROMOTE WEIGHT LOSS

FIELD OF THE INVENTION

The present invention is directed to dietary supplements comprising cinnamon, or extracts thereof or derivatives of the extracts thereof, and to methods of using these dietary supplements to enhance nutrient transport and to promote weight loss, both in humans and animals.

BACKGROUND

Type II diabetes is quickly becoming an epidemic in the United States. The increased incidence of Type II diabetes has been attributed to diets characterized by high fat intake and repeated ingestion of refined foods and sugars, coupled with low fiber and vegetable intake. Diet, along with the natural aging process, causes a deterioration in the way in which the body metabolizes blood glucose. When the body cannot properly metabolize blood glucose, a tendency to store glucose as fat typically occurs. This is one reason levels of body fat increase with age. Diabetes is also known to be associated with a variety of other ailments including heart disease, hypertension, and obesity. There is a known link between insulin resistance and increased visceral adiposity. Diabetes is also a leading cause of glaucoma and other conditions related to a decrease in the quality of life.

It has long been known that natural and/or synthetic substances may aid in controlling blood glucose and enhancing nutrient transport. Such substances act by a variety of mechanisms. For example, some substances act by mimicking the effects of endogenous insulin and are therefore capable of replacing endogenous insulin. Such substances include synthetic insulin injections such as those which are routinely prescribed to individuals with Type I diabetes. Other commonly prescribed substances known to mimic the effects of insulin include the naturally occurring compounds taurine, 4-hydroxyisoleucine, arginine, and vanadium. Although these compounds have been shown to work as insulin mimetics by acting in the body to decrease serum blood glucose levels, they have not been successfully developed into viable treatments for disorders of glucose metabolism.

Still other substances act directly to increase what is termed insulin sensitivity or glucose tolerance. Glucose intolerance forces the body to generate additional insulin in an effort to lower blood glucose. This causes stress on the beta-cells of the pancreas and is thought to be a key contributor to Type II diabetes. In a state of glucose intolerance, the body mechanism for disposing of blood glucose is not functioning at its optimum level and therefore the system is inefficient. Substances which increase insulin sensitivity or glucose tolerance by assisting the body in returning to optimal levels of blood glucose include alpha-lipoic acid, pinitol and myo-inositol. These substances cannot entirely replace the function of endogenous insulin, but work at the receptor level alongside endogenous insulin to increase insulin sensitivity or glucose tolerance. Here, the action is exerted directly on the Glut-4 receptor of the cell to trigger the cascade

normally caused by insulin that allows for the reduction in blood sugar via the transport of nutrients into the cell.

In the past, chromium was thought to aid in weight loss by controlling blood glucose and preventing the deposition of fatty acids. However, its actions were greatly limited and its claims never came to fruition. Cinnamon, known for its high concentration of chromium, has also been used for the control of blood glucose. However, researchers have demonstrated that cinnamon's effects are not from chromium, but rather from a different class of compounds. One study by Kahn et al. compared the chromium levels of foods and spices including cinnamon, and failed to find a correlation between chromium level and the level of insulin potentiation. (*Biological Trace Element Research*, 1990; 24:183-188). A meta-analysis by Althuis et al. showed no association between chromium and glucose or insulin concentrations. (*Am. J. Clin. Nutr.*, 2002; 76:148-55). A study by Broadhurst et al. has demonstrated that cinnamon is a strong potentiator of insulin in comparison to various other herbs and spices. (*J. Agric. Food Chem.*, 2000; 48:849-852).

One particular extract of cinnamon, methyl hydroxy chalcone polymer (MHCP), shows promising data in the area of glucose control. A recent study compared the effect of MHCP in 3T3-L1 adipocytes to that of insulin. (Jarvill-Taylor et al., *J. Am. College Nutr.*, 2001; 20:327-336). The results from that study support the theory that MHCP triggers the insulin cascade and subsequent transport of nutrients. The study also demonstrated that MHCP treatment stimulated glucose uptake and glycogen synthesis to a similar level as insulin. The study further demonstrated that treatment with endogenous

insulin and MHCP resulted in a synergistic effect. Due to these conclusions it is suggested that MHCP may prove to be a very valuable tool in the fight against diabetes, where insulin is present.

In addition to benefiting Type II diabetics, cinnamon may benefit individuals with impaired glucose tolerance (*i.e.*, pre-diabetics). Further, cinnamon has been shown to possess antioxidant activities related to lipid peroxidation. (Mancini-Filho et al., *Bollettino Chimico Farmaceutico*, 1998; 37:443-47). Cinnamon can be used as a food antioxidant and to enhance food palatability.

In broad terms, nutrient transport involves the deposit of nutrients into various tissues. For example, after the insulin cascade, the Glut-4 transport system triggered by insulin drives nutrients such as carbohydrates, amino acids (*e.g.*, glutamine, arginine, leucine, taurine, isoleucine and valine) and creatine into skeletal tissue. Typically, water is driven into the cells at the same time.

Creatine is a natural dietary component primarily found in animal products. In the body, creatine is stored predominantly in skeletal muscle, and mostly in the form of phosphorylated creatine, but also in its free state. Total creatine content of mammalian skeletal muscle (*i.e.*, creatine and phosphorylated creatine) typically varies from about 100 to about 140 mmol/kg. The level of creatine and phosphorylated creatine present in skeletal muscle can be increased through dietary supplementation with creatine.

The fuel for all muscular work in the body is adenosine tri-phosphate, or ATP. During intense exercise, ATP is utilized very rapidly. The body does not store much ATP in muscle so other substances must be broken down in order to replenish the ATP

that is rapidly broken down during exercise. If the ATP is not replenished, fatigue occurs and force/power production declines. Of all the substances in the body that can replenish ATP, the fastest is phosphorylated creatine. Thus, the primary function of phosphorylated creatine in muscle is to buffer ATP by preventing decreases in ATP during exercise.

Creatine is taken up into tissues, such as skeletal muscle, by means of an active transport system that typical involves an insulin dependent pathway. In a study by Stengee et al., insulin was co-infused along with creatine supplementation. (*Am. J. Physiol.*, 1998; 275:E974-79). The results of this study indicated that insulin can enhance creatine accumulation in muscle, but only if insulin levels are present at extremely high or supra-physiological concentrations. Stengee et al. refers to a previous study by Green et al. which involved experimentation with ingestion of creatine in combination with a carbohydrate-containing solution to increase muscular uptake of creatine by creating physiologically high plasma insulin concentrations. Stengee et al. reports that Green et al. had found the quantity of carbohydrate necessary to produce a significant increase in creatine uptake, as compared to creatine supplementation alone, was close to the limit of palatability.

Thus, there exists a need in the art for a viable method of increasing the uptake of creatine into mammalian tissue, such as skeletal muscle. Further, there exists a need in the art for a dietary supplement whose administration at normal physiological concentrations would effect such an increase in creatine uptake.

SUMMARY

Disclosed herein is: (a) a dietary supplement comprising cinnamon, or an extract thereof or a derivative of the extract thereof and a nutrient, or a derivative or a precursor thereof, with or without a carbohydrate; and (b) methods of increasing the uptake of nutrients in mammalian muscle, enhancing nutrient transport, and enhancing athletic performance comprising administration of said dietary supplement.

Accordingly, it is an object of the invention to provide a method and a dietary supplement which will enhance the uptake of nutrients into mammalian muscle. More specifically, it is an object of the invention to provide a method and a dietary supplement which will enhance the uptake of creatine into skeletal muscle. It is a further object of the invention to provide a method and a dietary supplement that triggers an insulin dependent pathway to enhance the uptake of creatine into skeletal muscle. It is a still further object of the invention to provide a method and a dietary supplement that achieves these objects when administered in physiologically acceptable amounts.

Also disclosed herein is: (a) a dietary supplement comprising cinnamon, or an extract thereof or a derivative of the extract thereof and (b) methods of losing weight and reducing body fat comprising administration of said dietary supplement.

Accordingly, it is also an object of the invention to provide a method and a dietary supplement which will promote weight loss and body fat reduction.

Other objectives, advantages and features of the invention will become apparent from the following detailed description, and from the claims.

BRIEF DESCRIPTION OF THE PREFERRED EMBODIMENT

The creatine-containing dietary supplements of the invention comprise cinnamon, or an extract thereof or a derivative of the extract thereof and creatine, or a derivative or a precursor thereof, with or without a carbohydrate.

Additionally, the body fat reduction and weight loss dietary supplements of the invention comprise cinnamon, or an extract thereof or a derivative of the extract thereof.

Cinnamon is one of the world's most popular spices. Cinnamon contains over one hundred different chalcones within it. Chalcones are a type of polyphenol or flavonoid. These chalcones may be extracted from cinnamon and isolated, and, optionally, derivatized. One chalcone which can be extracted from cinnamon is the phytochemical methyl hydroxy chalcone polymer, or MHCP. In a preferred embodiment of the invention, the dietary supplement includes MHCP.

The isolation of phytochemicals from cinnamon follows the general process of aqueous extraction followed by centrifugation to remove non-soluble compounds. Specifically, MHCP is extracted from cinnamon using the following process: 5 g cinnamon and 100 ml 0.1 N acetic acid are combined and autoclaved for 15 minutes. The resultant mixture is cooled, then centrifuged and the precipitate discarded. Four volumes of ethanol/0.1 N acetic acid are added to the supernatant and the mixture is stored overnight at 4 C°. The mixture is screened through a filter and then introduced onto an LH-20 column and washed with 600 ml ethanol/0.1 N acetic acid. The desired fraction is then eluted with a 1:1 mixture of acetonitrile and 0.2 N acetic acid. The eluent is then concentrated and introduced onto a HPLC column at 275 nm.

The chemical name for creatine is methylguanidino acetic acid. This is the free form of creatine. Known creatine derivatives include creatine monohydrate and other hydrates, creatine salts such as creatine citrate, creatine esters, phosphorylated creatine, and creatine pyruvate. Known creatine precursors include glycocyamine or Guanidineacetic Acid and the amino acids arginine, glycine, and methionine. In a preferred embodiment of the invention for the creatine-containing dietary supplements, the dietary supplement includes creatine monohydrate.

The optional carbohydrate in the creatine-containing dietary supplements of the invention include simple sugars such as the monosaccharides glucose and dextrose.

Typical formulations of creatine-containing dietary supplements according to the invention include: dietary supplements containing from about 1 mg to about 100 mg of cinnamon extract or cinnamon extract derivative per gram of dietary supplement; dietary supplements containing from about 1 mg to about 400 mg of creatine or creatine derivative or creatine precursor per gram of dietary supplement, and preferably from about 50 mg to about 125 mg of creatine or creatine derivative or creatine precursor per gram of dietary supplement; dietary supplements containing from about 10 mg to about 950 mg of carbohydrate per gram of dietary supplement, preferably from about 400 mg to about 900 mg of carbohydrate per gram of dietary supplement, and more preferably from about 500 mg to about 800 mg of carbohydrate per gram of dietary supplement.

Typical formulations of the body fat reduction and weight loss dietary supplements of the invention include dietary supplements containing from about 1 mg to

about 1,000 mg of cinnamon extract or cinnamon extract derivative per gram of dietary supplement.

Typical daily dosages of the creatine-containing dietary supplements of the invention are about 10 mg to about 10,000 mg of cinnamon extract or cinnamon extract derivative and about 100 mg to about 25,000 mg of creatine or creatine derivative or creatine precursor, and preferably about 500 mg to about 10,000 mg of creatine or creatine derivative or creatine precursor. Generally, the creatine-containing dietary supplements of the invention are administered in an amount of from about 200 mg to about 500 g per day.

Typical daily dosages of the body fat reduction and weight loss dietary supplements of the invention are about 10 mg to about 10,000 mg of cinnamon extract or cinnamon extract derivative. Generally, the body fat reduction and weight loss dietary supplements of the invention are administered in an amount of from about 100 mg to about 500 g per day.

The dietary supplements of the invention are orally administered and can be in the form of capsules, tablets, powdered beverages, bars, gels or drinks.

Administration of the dietary supplements of the invention will mimic the effects of insulin and will decrease glucose intolerance, thereby increasing the efficiency of insulin. As a result, administration of the creatine-containing dietary supplements of the invention will enhance the transport of creatine into tissues such as skeletal muscle. The increase in the amount of creatine storage in the muscle can be measured by muscle biopsy. Upon administration of the creatine-containing dietary supplements of the

invention for a period of days (*e.g.*, for as little as 4 days and as many as 30 days), the total creatine content of skeletal muscle (*i.e.*, free and phosphorylated creatine) will increase from about 10% to about 40% where typical levels of total creatine in skeletal muscle prior to administration are between about 100 to about 140 mmol/kg of dry muscle.

Administration of the body fat reduction and weight loss dietary supplements of the invention, particularly to individuals with impaired glucose tolerance, will have the effect of restoring optimal glucose functioning, therefore lessening the likelihood of adipose storage, and leading to a reduction in body fat and weight.

ABSTRACT

Materials derived from cinnamon can be administered orally to humans or animals for the purpose of controlling blood glucose as well improving glucose tolerance. Controlling glucose metabolism is essential for those with impaired glucose metabolism as is the case for those with Type II diabetes where insulin function is not properly functioning. Such administration can also be used for the purpose of enhancing nutrient transport for purposes of athletic performance and controlling bodyweight and body fat levels. Similarly related, such administration can also be used for the purpose of enhancing creatine transport into excitable tissues such as skeletal muscle. The material can be administered as extracts of cinnamon and can be administered in a variety of ways including capsules, tablets, powdered beverages, bars, gels or drinks.

[redacted]